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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,344

04/04/2008

Lawrence Solomon

SLP-036

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EXAMINER

LOVE, TREVOR M

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

11/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,344	Applicant(s) SOLOMON ET AL.	
	Examiner TREVOR M. LOVE	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/01/2007, 06/01/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-13 are pending and are under consideration.

Claim Objections

Claim 10 is objected to because of the following informalities: There are two periods "." at the end of claim 10. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "the D/d ration". There is insufficient antecedent basis for this limitation in the claim. Furthermore, the terminology is unclear for failing to establish the metes and bounds of claim 8. Claim 8, or the rest of the disclosure, fails to clearly distinguish what exactly the D/d ration is referring to.

Claims 9 and 11 are rejected as depending from indefinite claim 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieberman, Herbert (Pharmaceutical Dosage Forms – tablets, 1990) in view Geller, Ehud (U.S. Patent number 3,927,194).

Lieberman, in section "IV. Layer Tablets" first paragraph, discloses layered tablets wherein the layers are "sandwiched" on top of each other, and the edges are exposed (such as instant claim 3). Said layered tablets are disclosed as 2 or 3 layers of granulation compressed together. Lieberman teaches that layered dosage forms have the advantage of being able to separate two incompatible substances with an inert

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barrier (such as instant claim 5), or instead of modifying the active ingredient, they can be used to modify the release profile, each layer can comprise components that determine either immediate, intermediate, or slow release of the active. Furthermore, Leiberman discloses that the layered tablet method allows for the weight of each layer to be accurately modified. The multilayer tablets are also disclosed as being capable of having "distinctive markings" impressed on the surface. Leiberman, in the section discussing the "Properties of Tablets" discloses under point "4" that tablets can contain markings. Said markings may appear as a score or crease across the face, which is intended to permit breaking the tablet into equal parts for administration. Leiberman, however, states that substantial variation can occur in manually broken tablets.

Leiberman fails to directly envisage that the score on the multilayer tablet extends at least 70% of the distance of the first segment of said multilayer tablet.

Geller teaches a tablet which is scored sufficiently to form a groove which is $1/3$ to $2/3$ the depth of the total tablet thickness. This groove being designed to facilitate separation into subdivisions containing substantially equal amounts of pharmaceutically active ingredients (see claim 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the groove of Geller in the tablets of Leiberman. One would have been motivated to do so with a reasonable expectation of success since both Leiberman and Geller teach that tablets can be scored in order to facilitate breaking the tablet into equal parts for administration.

With regards to claims 1, 2 and 10, it would have been obvious to one of ordinary skill in the art to optimize the thickness of each layer; this is directly taught by Leiberman (see page 274, section IV, first paragraph). One would have been motivated to do so to minimize the amount of the first layer that was involved in the breaking of the tablet with the intent of reducing the variability in the concentration of the components of the top layer.

With regards to claim 3, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have all three layers be directly atop one another. One would have been motivated to do so since Leiberman teaches a two or three layer composition wherein the components have the appearance of a sandwich because the edges of each layer are exposed (see page 274, section IV first paragraph).

With regards to claims 4-7, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the contents of the different layers. One would have been motivated to use different actives in the different layers since Leiberman teaches one motivation for layering is the separation of incompatible layers, which would obviously contain different substances, at least three to achieve effective separation (see page 274, section IV, first paragraph). In the same paragraph Leiberman teaches that another motivation for layering is varying the speed of release of the different coatings. Leiberman directly teaches three coatings, all with different release rates: immediate, slow release, and intermediate release.

With regards to claim 12, it would have been obvious to one of ordinary skill in the art at the time the invention was made to divide the tablet to allow for smaller doses of the active ingredients. One would have been motivated to do so since Leiberman directly teaches the use of scoring "to permit breaking the tablet into equal parts for the administration of half a tablet" (see page 132, section I, point 4). It would be obvious to administer a smaller dose portion of a tablet to a patient in need there of.

With regards to claim 13, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize drugs directed towards the treatment of cardiovascular conditions. One would have been motivated to do so since Geller discloses that the scoring method taught in Geller is "directed principally to the application of specific pharmaceutical formulations incorporating isosorbide dinitrate as the active ingredient", but is applicable to other actives as well. Isosorbide dinitrate being a potent coronary vasodilator (see column 2, lines 28-33).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-7, and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-11, 13-18, of copending Application No. 11/441455 .

Although the conflicting claims are not identical, they are not patentably distinct from each other because application '455 anticipates the product of the instant claims by disclosing a an immediate release partial dose of a drug contained in a segmented dosage form by breaking a tablet through a score, wherein a first segment contains a drug, and a second segment can either contain a drug or be drug free, comprising a score at least 50%, and preferably 70%, through said first segment (claims 2, 3, 5, 6, 13, 14, 15, 16, 17, and 18 read on instant claims 1 and 10). '455 also discloses a method wherein the tablet contains a third layer, said third layer being adjoined at a face of said second segment opposite the interface of said first and second segments wherein said third segment contains the same drug as the first segment (claims 7, 8, and 9 read on instant claims 5, 3, and 4, respectively, claim 19 also reads on claim 3). Furthermore, '455 discloses that the second segment can contain different drugs from those contained in the first segment, or that the second segment can contain the same drug as the first segment, but in a different weight ratio (claims 10 and 11 read on instant claims 6 and 7, respectively).

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This rejection is anticipatory because application '455 teaches a method of using a composition, and said composition is described as being the composition of the instant ~~claims~~. The method therefore anticipates the product.

Deleted: claims .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed. All claims are rejected. No claims are objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
November 14, 2008